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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/530,800 | 03/13/2006 | Chaim M. Roifman | 213202-00618 | 4283 |
| 27160 7590 01/28/2010 KATTEN MUCHIN ROSENMAN LLP (C/O PATENT ADMINISTRATOR) 2900 K STREET NW, SUITE 200 WASHINGTON, DC 20007-5118 | | | | |
| EXAMINER | | | | |
| FINN, MEGHAN R | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1614 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,800

Applicant(s)

ROIFMAN ET AL.

Examiner

MEGHAN FINN

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's Amendment filed November 17, 2009 has been received and entered into present application. Claims 8, 12-16 and 57 were canceled and no claims were added by applicant. Thus claims 1, 4, 7 and 58-60 are pending.

Applicants' arguments, filed November 17, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 7 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roifman et al. (WO 01/79158 A2, cited on applicant's IDS) in view of Foekens et al. (Cancer Research, 2001, Vol. 61, Pages 5407-5414), each already of record, for the reasons set forth at pages 6-9 of previous office action dated April 24, 2009, of which reasons are herein incorporated by reference.

Applicant has amended claims 1 and 4 to remove "solvate or hydrate" and to make claim 58 depend from claim 1 instead of claim 57 which is now canceled. As in the previous office action, the claims read upon administering the elected species, CR4, to an animal in need of vascular endothelial growth factor (VEGF) inhibition. As discussed previously, Roifman et al. teaches administration of CR4 to inhibit cell proliferation and its use to treat any type of cancer (page 5, lines 6-15). Breast cancer is, among others, a cancer in which patients have elevated VEGF levels as taught by Foekens et al. (page 5407, column 2). As discussed before, it would have been obvious to use CR4 from Roifman et al. to treat breast cancer and breast cancer patients are those in need of inhibition of VEGF, as taught by Foekens et al. Thus treatment of the same patient population with the same drug, which would thus have the same effect, is suggested by the prior art. Applicant has argued that their unexpected discovery that these compounds are capable of inhibiting VEGF makes the claims novel and unobvious but a significant scientific discovery and a being patentable over the prior art

are not the same thing. The prior art does not have to disclose why something works or even teach the same motivation as applicant as long as the method is suggested by the prior art it would necessarily have the same effect. Applicant has made the argument that a person of skill in the art would not combine these references and if they did any such combination would not result in the claim subject matter. Applicant has not clarified why it would not result in the same subject matter, as discussed above treatment of a patient with breast cancer reads upon applicant's claimed invention.

Applicant argues that one of skill in the art who read Roifman et al. would not turn to a reference such as Foekens because there is no discussion of VEGF in Roifman et al. and the compounds are not the same in Foekens. Foekens was cited as an evidence-type of document to show that a breast cancer patient is one who is in need of inhibition of VEGF, and furthermore both references are directed towards cancer treatments and VEGF is known to be involved in cell proliferation so one of skill in the art would find the two references relevant to each other.

Applicant's arguments have been carefully and fully considered but are not deemed persuasive and thus the rejection of claims 1, 4, 7, and 58-60 is **maintained.**

Conclusion

Rejection of claims 1, 4, 7 and 58-60 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614